MAY - 7 2012

Free Wheelchair Mission®
TRANSFORMING LIVES THROUGH THE GIFT OF MOBILITY

510(K) SUMMARY (21 CFR 807.92)

GEN_2 MECHANICAL WHEELCHAIR

510(k) Owner:	Free Wheelchair Mission 15279 Alton Parkway, Suite 300 Irvine, CA 92618 Tel: 949-273-0858 Fax: 949-273-8471
Contact Person:	Sharon Rockwell Tel: 714-695-9269 E-mail: srockwell@writeme.com
Date Prepared:	December, 2011
Trade Name:	GEN_2 Mechanical Wheelchair
Common Name:	Mechanical Wheelchair
Classification Name:	Mechanical wheelchair per 21 CFR 890.3850, IOR
Predicate Devices:	Ki Mobility Catalyst Wheelchair, K062660
Device Description:	The GEN_2 mechanical wheelchair is a highly adaptable all-purpose wheelchair created for use in developing countries, while allowing for a healthy, personalized fit. The wheelchair features adjustable seating, large castor wheels, an extra-thick cushion and adjustable footrests.
Intended Use:	The GEN_2 is a manually operated device intended to provide mobility for persons restricted to a sitting position. The Indications for Use are identical to those of the predicate devices.

Technological Characteristics:

Technological Characteristics: The GEN_2 mechanical wheelchair is substantially equivalent in design, materials, and intended use to the Ki Mobility Catalyst mechanical wheelchair as described in the table below:

Feature	Catalyst	GEN_2
Intended Use	As a means of mobility for persons restricted to a sitting position.	To provide mobility to persons restricted to a seated position.
Frame material	6061-T6 Aluminum	Powder coated steel frame that meets ASTM A 53/A 53M-2005 and JIS G 3444-2004 standards
Frame widths	14-20"	13.5-19.5"
Overall widths	20.5-26.5"	29"
Seat depths	14-20"	11.5-17"
Back heights	8.5-19"	11.8-19"
Weight limit	220 lbs	220 lbs
Chair weight	23 lbs (without footrests)	36 lbs (with footrests)
Armrests	Flip back height adjustable desk and full length arm pads. Tubular swing-away.	Fixed in place to serve as armrests but not to restrict transfers.
Front end type	Swing-away, non-swing-away	Swing-away
Back type	Standard	Standard
Footrest hangers	70°, elevating leg rest	NA
Footplates	Composite, foam, angle adjustable	Polypropylene, 280 mm adjustable range with angles adjustable to 0, ± 7°, ± 14°, and ± 21°.
Extension tubes	Extra short, short, med, long	NA
Back upholstery	Low, med, tall, adjustable	Adjustable to 4 different heights
Axle plates	Standard, curved, amputee, offset	NA
Wheel sizes	22, 24, 26	26"
Wheel types	Spoke, composite mag, Octopus (performance spoke)	Spoke
Tire types	Pneumatic, full profile polyurethane, iron cap (puncture resistant), high pressure	Pneumatic
Handrims	Aluminum, plastic coated projections	Powder coated steel

Feature	Catalyst	GEN_2
Caster sizes	4, 5, 6, 8"	8"
Caster types	Poly, pneumatic, pneumatic with airless insert	Polypropylene
Forks sizes	4, 5, 6, 7" frog legs	5"
Wheel locks	Push to lock, pull to lock, low profile	Pull to lock
Anti tips tubes	Yes	No
Standards applied	Static Stability and Fatigue Strength, ANSI/RESNA std sections 1, 5, 7, 8, 16 and 93	ISO 7176-1, 3, 5, 7, 8, 15, 16
Tubing wall thickness	0.070" on frame except front vertical tube which is 0.1". X-tube is 0.070"	0.079" throughout
Tube properties	6061-T4 prior to welding. After welding, the component is treated up to T-6.	ASTM A 53/A 53M-2005 JIS G 3444-2004

The indications for use for the GEN_2 and the predicate device are identical. The size ranges in terms of frame width, seat depth, back depths, chair weight and weight limit overlap those of the predicate device. Most other features are very similar. The fundamental technology, welded tube frame, fire retardant upholstery, and wheel locks are the same. The information provided supports a substantial equivalence decision. Any differences in features to the predicate do not affect the performance of the device and do not raise new types of safety or effectiveness questions.

Non-Clinical Performance Data:

Non-clinical testing has been performed to mechanical wheelchair international standards including:

1) ISO 7176-1:1999 Determination of static stability
2) ISO 7176-3:2006 Determination of effectiveness of breaks
3) ISO 7176-5:2008 Determination of dimensions, mass and manoeuvring space
4) ISO 7176-7:1998 Measurement of seating and wheel dimensions
5) ISO 7176-8:1998 Requirements and test methods for static, impact and fatigue
6) ISO 7176-15:1996 Requirements for information disclosure, documentation and labeling
7) ISO 7176-16: 1997 Resistance to ignition of upholstered parts -- Requirements and test methods

The ISO tests were conducted with methods that met the following standards:
1) ISO 7176-11:1992 Test dummies
2) ISO 7176-13: 1989 Determination of coefficient of friction of test surfaces

Conclusions: The non-clinical test results demonstrate the GEN_2 Mechanical Wheelchair does not raise any issues regarding safety and effectiveness. The testing supports a determination of substantial equivalence to mechanical wheelchairs previously cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Free Wheelchair Mission
% Ms. Sharon Rockwell
Consultant
5582 Chalon Road
Yorba Linda, California 92886

MAY - 7 2012

Re: K113713
Trade/Device Name: Free Wheelchair Mission GEN_2 Mechanical Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: March 26, 2012
Received: March 27, 2012

Dear Ms. Rockwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Free Wheelchair Mission GEN_2 Mechanical Wheelchair

Indications for Use:

The GEN_2 Mechanical Wheelchair is intended to provide mobility to persons restricted to a seated position.

Prescription Use ____ ___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113713